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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,549	02/28/2002	Brigitte Chau Phan	BT12 00102703(USP3) USP8	3006
20995	7590	04/27/2004	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			JOHANNSEN, DIANA B	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 04/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/087,549

Applicant(s)

PHAN ET AL.

Examiner

Diana B. Johannsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 2-6, 8, 10 and 12-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 7, 9 and 11 is/are rejected.
- 7) ☒ Claim(s) 7, 9 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. This application has been transferred from Examiner E. Whisenant to Examiner D. Johannsen. The application remains assigned to Art Unit 1634.

### ***Election/Restriction***

2. Applicant's election without traverse of Group I, claims 1 (in part), 7, 9, and 11, in the Response filed March 18, 2004 is acknowledged.
3. Claims 2-6, 8, 10, and 12-15, as well as claim 1 to the extent that it is drawn to an antigen-antibody binding assay, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the Response of March 18, 2004.

### ***Oath/Declaration***

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

In particular, it is noted that the Oath/Declaration filed July 15, 2002 includes a non-initialed, non-dated alteration of one inventor's address. Applicant's attention is drawn to MPEP 605.04(a), which states that "The Office will not consider whether noninitialed and/or nondated alterations were made before or after signing of the oath or declaration but will require a new oath or declaration."

***Specification***

5. The abstract of the disclosure is objected to because it exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

***Claim Objections***

6. Claims 7, 9, and 11 are objected to because of the following informalities: the term “complementary” is misspelled “complimentary” in each of the claims. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 7, 9, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite over the recitation of the step “mixing said capture beads and said reporter beads under binding conditions so as to permit formation of a dual bead complex if said target agent is present in the sample, the reporter bead and capture bead each being bound to the target agent.” As the claim does not require or recite a step of, e.g., mixing or combining the sample containing the target agent and/or the target agent itself with the capture beads and/or reporter beads, it is unclear as to how a step of mixing the two types of beads would result in binding of the beads to the target agent. Further, it is unclear from this language as to whether the two types of

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beads come into contact with the sample, or whether they, e.g., bind to target agent that has previously been separated from the sample. Clarification is required.

Claim 7 is indefinite over the recitation of the phrase “depositing said test sample in a flow channel of an optical bio-disc which is in fluid communication with a target zone.” It is unclear as to whether this language is intended to indicate that the “flow channel” is in fluid communication with a target zone which is also located within the optical bio-disc, or whether this language is intended to indicate that the optical bio-disc “is in fluid communication with a target zone” at some other location (i.e., not within the bio-disc). Clarification is required.

Claims 9 and 11 are indefinite over the recitation of the phrase “depositing a plurality of capture beads and reporter beads in a mixing chamber” in each of the claims. It is unclear whether this language is intended to refer back to the previously recited “plurality of reporter beads” and “plurality of capture beads,” or whether this step is intended to encompass a different “plurality of capture beads and reporter beads.” Clarification is required.

Claims 9 and 11 are indefinite over the recitation of the limitation “the mixing chamber of an optical bio-disc” in each of the claims because there is insufficient antecedent basis for this limitation in the claims. While claims 9 and 11 do previously refer to a “mixing chamber,” the claims do not previously refer to or recite a “mixing chamber of an optical bio-disc.” Further, because the claims as written do not clearly require that the plurality of beads and the test sample be deposited in the same mixing

chamber, it is further unclear how the beads and the sample actually come into contact so as to allow binding of target DNA to signal and transport DNA to occur.

Claims 9 and 11 are also indefinite over the recitation of the limitation “the mixing chamber of an optical bio-disc which is linked to a target zone by a connecting flow channel” in each of the claims. It is unclear as to whether this language is intended to indicate that the “mixing chamber” is linked to a target zone which is also located within the optical bio-disc, or whether this language is intended to indicate that the optical bio-disc “is linked to a target zone” at some other location (i.e., not within the bio-disc). Clarification is required.

Claims 9 and 11 are indefinite over the recitation of the limitation “the capture zone” because there is insufficient antecedent basis for this limitation. While the claims previously refer to a “target zone” that includes capture agents, no prior reference is made to a “capture zone.”

### ***Conclusion***

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Virtanen (US 6,030,581 A [2/2000]) disclose optical disks adapted for use in detecting analytes of interest, as well as detection methods in which such disks are employed (see entire reference). However, while Virtanen discloses embodiments in which beads/spherical substrates are employed in detection of analytes via an analyte-mediated attachment between the beads and a surface of the disk, there is no disclosure in the reference of a multiple or dual bead assay. Further, Virtanen indicates that sensitive detection may be achieved using a single type of bead, and

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there is no suggestion in the reference or in the prior art of any need for an additional type of bead to effect or improve detection using Virtanen's disk. Sibbald (WO 98/13684 [4/1998]) discloses a rotating, disc-shaped apparatus that is employed in analysis of biological samples (see entire reference). However, while Sibbald discloses the use of beads in their apparatus, and teaches that the use of beads for substrate binding is advantageous in that beads expose a large surface area to the sample and induce a "natural turbulence" (see entire reference, particularly pages 4-5), there is no disclosure in Sibbald of an assay in which multiple types of beads become linked to one another by virtue of each binding to a target molecule, and no suggestion in the art that the use of such multiple beads would improve detection as it is conducted in Sibbald's apparatus.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long horizontal flourish.

Diana B. Johannsen  
Patent Examiner  
April 23, 2004